

# UNITED STATES PATENT AND TRADEMARK OFFICE

In re Novartis AG  
Request for Patent Term Extension  
U.S. Patent No. 4,559,332


:  
: **ORDER GRANTING**  
: **INTERIM EXTENSION**

On November 5, 2002, Novartis AG, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,559,332, filed an application under 35 U.S.C. § 156, requesting an extension of 1,218 days. The patent was originally extended for a period of one year pursuant to 35 U.S.C. 156(e)(2) from April 9, 2004, until April 9, 2005, and extended again for a period of one year from April 9, 2005, to April 9, 2006. The patent claims the active ingredient eplerenone in the human drug product "INSpra®" and a method of use of said product. The application indicates that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the extended date of expiration of the patent, interim extension of the patent term is appropriate.

A third interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,559,332 is granted for a period of one year from the extended expiration date of the patent, until April 9, 2007.

4/5/06  
Date

  
Jon W. Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office